Abbreviated 510(k) Notification

510(k): Surveyor Central Station System Device Summary

Submitter: **Date: November 26, 2013**

Amy Yang, Regulatory Affairs Engineer
Mortara Instrument, Inc.
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DEC 0 3 2013

Trade Name: Mortara Surveyor Central Station
Common Name: Central Station
Classification Name: Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)
Classification Description: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Classification Regulation: 21 CFR §870.1025
Product Code: MHX

Legally marketed devices to which S.E. is claimed:

Mortara Surveyor Central Station	Predicate 510(k) Number	Predicate Manufacturer / Model
Patient Monitoring	K060135	Mortara Instrument, Inc. / Surveyor Telemetry Central Station
Electrocardiograph	K082946	Mortara Instrument, Inc. / ELI 350 Electrocardiograph

Description:

The system architecture of the Surveyor Central Station system is flexible and can be supported on a single workstation computer or multiple workstation computers along with a separate optional storage server. Each workstation can display information for a variable number of patients. Multiple workstations can be combined to expand the system capacity. All data received for all patients is stored and available for review.

Cardiac parameters and functions supported through interface with patient monitors include 3 or 5 lead ECG as well as 12-lead ECG along with interpretation plus continuous monitoring and management of arrhythmia and ST alarms generated by the patient monitor. Cardiac parameters and functions supported through interface with telemetry systems include 12-lead ECG along with interpretation plus continuous monitoring, alarming and management of arrhythmia and ST generated by the Surveyor Central.

Other parameters received from patient monitors or telemetry systems can include invasive pressures, non-invasive blood pressure, pulse oximetry, CO2 capnography, respiration, temperature, cardiac output and hemodynamic calculations including relevant values, indices and waveforms.

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Technology Comparison:

The Mortara Surveyor utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use:

The Surveyor Central Station system is intended for monitoring of physiological waveforms, including cardiac and vital signs, for multiple patients within a medical facility. The system can receive, display and store data from multi-parameter patient monitors and/or telemetry systems. The system can support patient monitoring and telemetry monitoring modes simultaneously. Patient monitors can be the Surveyor S12 and S19 patient monitoring systems (K123556) or other compatible patient monitors. Ambulatory telemetry transmitter sources can be the X12+ (K974149) and T12/T12S (K022618) systems or other compatible telemetry transmitters.

In patient monitoring mode, the patient monitors will provide primary monitoring functionality while the Surveyor Central Station system provides continuous secondary monitoring of patients including alarm reception and management, display and storage of parameters and waveforms including full-disclosure, automatic and on-demand generation of various printed reports using a network-attached printer.

In telemetry monitoring mode, the Surveyor Central Station will provide primary monitoring of patients including display of values and waveforms, alarm generation and management, data storage, patient management and report printing functionality. Patients are monitored through telemetry, when moving in a defined area, of a variable size depending on system layout. In order to provide proper coverage, an antenna network can be installed according to customer needs.

The data and analysis provided by the Surveyor Central Station is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various conditions.

Indications for Use:
The Mortara Surveyor Central Station is indicated for use in adult & pediatric patient populations.

- In a clinical setting, by qualified medical professionals, properly trained for patient monitoring and use of the system. Continuous analysis is provided for all patients. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements.
- Centralized monitoring through a network of patients in Coronary Care Units, Intensive Care Units, Ambulatory Care Units (Telemetry Units), Step-Down Units, Operating Rooms, Emergency Departments and Surgical Centers. Evaluation of adult and pediatric patients with symptoms suggesting arrhythmia. Detected arrhythmias create an audiovisual alarm according to the alarm profile.
- Chest Pain Evaluation.
- Evaluation of patients with pacemakers.
- Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of monitored parameters documenting therapeutic interventions in individual patients or groups of patients.
- Clinical and epidemiological research studies.

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Performance Testing:
Sterilization Validation:
The Mortara Surveyor Central Station is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.

Shelf Life Testing:
The Mortara Surveyor Central Station is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.

Biocompatibility Testing:
The electrodes, transmitter and monitor housing and patient cable are parts of the system that come in contact with the patient. These component devices have been previously tested in their own right for other submissions and found to be acceptable. However, the Surveyor Central Station itself does not involve direct / indirect patient contact.

Software Testing:
Software for the Mortara Surveyor Central Station was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Mortara Surveyor Central Station complies with its predetermined specification.

Electrical Safety:
The Mortara Surveyor Central Station was evaluated for patient safety in accordance with applicable Standards.

Electromagnetic Compatibility Testing:
The Mortara Surveyor Central Station was tested for EMC in accordance with applicable Standards. Test results indicated that the Mortara Surveyor Central Station complies with its predetermined specification.

Performance Testing – Bench:
The Mortara Surveyor Central Station was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional.

Performance Testing – Animal:
Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Surveyor Central Station.

Performance Testing – Clinical:
Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Surveyor Central Station.

Conclusion:
Based upon a comparison of devices and performance testing results, the Mortara Surveyor Central Station is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 3, 2013

Mortara Instrument, Inc.
% Amy Yang, BSBE, MBA, RAC
Senior Regulatory Affairs Engineer
7865 North 86th St.
Milwaukee, WI 53224 US

Re: K131929
Trade/Device Name: Surveyor Central Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: October 18, 2013
Received: October 21, 2013

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638.2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen D Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131929

Device Name: **Mortara Surveyor Central System**

Indications for Use:

The Surveyor Central System is indicated for use:

- In a clinical setting, by qualified medical professionals, properly trained for patient monitoring and use of the system. Continuous analysis is provided for all patients. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements.
- Centralized monitoring through a network of patients in Coronary Care Units, Intensive Care Units, Ambulatory Care Units (Telemetry Units), Step-Down Units, Operating Rooms, Emergency Departments and Surgical Centers. Evaluation of adult and pediatric patients with symptoms suggesting arrhythmia. Detected arrhythmias create an audiovisual alarm according to the alarm profile.
- Chest Pain Evaluation.
- Evaluation of patients with pacemakers.
- Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of monitored parameters documenting therapeutic interventions in individual patients or groups of patients.
- Clinical and epidemiological research studies.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Digitally signed by Faris -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)